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PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
5100 WISCONSIN AVENUE, N.W., SUITE 400
WASHINGTON, DC 20016
T: (202) 686-2210 F: (202) 686-2216
PCRM@PCRM.ORG WWW.PCRM.ORG

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Michael O. Leavitt, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on the HPV test plan for the asphalt category

Dear Administrator Leavitt:

The following comments on the American Petroleum Institute's Petroleum HPV Testing Group's (API) test plan for the asphalt category are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

API submitted its test plan on December 15, 2003 for the asphalt category, which is composed of several different chemical entities of varying composition. The authors propose a combined inhalational developmental/reproductive test (OECD 421). This test will kill at least 675 animals. This test plan is an extreme example of check-the-box toxicology, as the OECD 421 is being conducted only to fill a gap in the SIDS data set, without regard to other available information about the chemical as a whole. The proposal therefore violates the October 1999 animal welfare provision that specifically states that "In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested."

According to the test plan, the asphalt category chemicals' high molecular weights, high viscosity, low solubility, and low vapor pressure result in minimal toxicological activity. The primary toxicological endpoints of concern in any subchronic study will be irritation of the nasal passages and lungs. This is realized in the results of the two subchronic studies already performed, where no histopathological effects were observed on any reproductive organs, but nasal irritation was noted. Further, we agree, as the test plan states, that since refining processes and "...generating conditions (temperature, degree of agitation, and duration of heating)" can significantly affect the test matter and its toxicity, the predictability of results of a laboratory animal study is minimal.

Asphalts are widely used in an occupational setting. A National Occupational Heath Survey in 1974 led NIOSH to estimate that over 2 million workers were exposed to asphalts and asphalt fumes (IARC, 1985). A TOXLINE database search yields 1042 entries. AGCIH (1986) states that "No significant differences in health were found between asphalt workers and a group of controls at 25 oil refineries...no evidence that exposure to asphalt affected the health of workers in roofing, manufacturing, paving operations, and interstate trucking over asphalt highways." Though anecdotal, one could use a weight-of-evidence approach and conclude that an absence of reproductive or developmental effects over the years points in the direction of a lack of such effects. Further, it can be argued that the HPV Chemical Challenge Program is an inappropriate venue for determining the toxicity profile for asphalt fumes. An agency such as OSHA/NIOSH would be better suited for examining any possible reproductive or developmental effects of asphalt fumes in humans, using epidemiological study methodologies.

Perhaps the best argument against conducting an OECD 421 on the asphalt category can be found in the API's own test plan. On page 15, they state:

> "However, considering the high molecular weight, limited bioavailability and minimal observed general toxicity of whole asphalts, they are unlikely to cause developmental of reproductive effects. Since the toxicity from asphalt fumes appears correlated with the concentration of 3-7 ring PAC in the condensate...it should be possible to estimate the potential for reproductive/developmental toxicity from results of studies already performed with aromatic extracts and heavy fuel streams which are the subjects of other HPV test plans."

Inexplicably, the API then proposes to conduct an OECD 421.

The animal protection community has previously commented on similar plans submitted by the API, noting in particular the continuous nature of petroleum products (Petroleum coke, Lubricating oils, Waxes, Gasoline Category, Petroleum Napthas, Petroleum Gas). The common theme in all these plans is that the primary toxicity of these complex chemical mixtures is generally due to either specific compounds that are already well characterized (e.g., BTEX or PAH compounds) or to the overall physical properties of the mixture as oily materials. The toxicity of these classes of materials has been extensively studied both through animal testing and human exposure studies (ATSDR,1995; ATSDR, 1999; McKee et al, 1987; IPCSWHO, 1982). We have therefore disagreed with the proposed animal testing in all of the API's previous plans.

We must once again repeat our concerns and cite several specific categories that have very similar composition. The API's own Crude Oil Category test plan lays out this argument quite well:

> "There is a substantial body of data on products derived from crude oils, such as gasoline, diesel fuels, kerosene and jet fuels, lubricating oils and white oils, which are subjects of other HPV test plans. Extrapolation from these studies provides insight into biologically active components of crude oils. Occurrence and severity of toxic effects appear correlated with concentration of polynuclear aromatic

hydrocarbons (PAH) and PAH-containing nitrogen or sulfur heteroatoms (PAC). In addition there are significant data developed from monitoring effects of unintentional oil spills, providing 'real world' environmental information."

Asphalts share many similar toxicological characteristics and contain the same toxic moieties as substances found in the previously submitted API categories of crude oils, lubricating basestocks, waxes, and gas oils, as well as in the higher olefins category proposed by the ACC Olefins Panel. The ACC provided abundant information that showed there was no need to conduct further reproductive/developmental testing on these compounds. These substances have all been thoroughly studied, are well-characterized including their reproductive and developmental effects, and there is an abundance of human exposure data on them as well. In short, an understanding of the toxicity of these specific compounds and of similar mixtures containing these compounds already exists.

We request that the API amend its test plan, using thoughtful toxicology to fulfill endpoints, instead of conducting another animal test that will do nothing to predict possible hazards to workers. Thank you for your attention to these comments. We may be reached at 202-686-2210, ext. 335, or via e-mail at kstoick@pcrm.org.

Sincerely,

Kristie M Stoick, M.P.H.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Research

Literature cited:

ACGIH. (1986). Documentation of the Threshold Limit Values and Biological Exposure Indices, 5th ed. Cincinnati, OH. AGCIH.

ATSDR. (1995). Toxicological Profile For Polycyclic Aromatic Hydrocarbons (PAHs). Prepared By Research Triangle Institute for the U.S. Department Of Health And Human Services. Public Health Service.

ATSDR. (1999). Toxicological Profile For Total Petroleum Hydrocarbons (TPH). Prepared by Research Triangle Institute for the U.S. Department Of Health And Human Services Public Health Service.

McKee, R.H. et al (1987). Developmental toxicity of EDS recycle solvent and fuel oil. Toxicol 46, 205-215.

IARC. (1985). Monographs of Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, IARC, 1972-PRESENT V 35 54.

IPCS/WHO. (1982). Environmental Health criteria 20: Selected petroleum products.Geneva: World Health Organization.